The European Commission must preserve vital antibiotics for human health and protect animal welfare

Despite concerns expressed by health professionals (supported by human health and animal welfare organisations), on 19 April the European Commission proposed a <u>draft list of antimicrobials to be reserved for human health</u> that will not protect human health nor animal welfare.

Under the 2019/6 regulation, the European Commission is required to draft a list of antimicrobials that will be restricted to human-use only to preserve the most critically-important drugs for human health. The antibiotics proposed by the European Commission, however, are not currently authorised for veterinary use in food production in the EU, so adding these drugs to the list will not change intensive farming practices that rely on antimicrobial use and will not help curb the rising threat of antimicrobial resistance (AMR). The proposed list undermines the purpose of Regulation (EU) 2019/6 to establish actions that restrict the use of critically important antimicrobials for human health.

The European Commission's proposed list is based on <u>the European Medicines</u> <u>Agency (EMA)'s recommendation</u>, published in February 2022. Though the EMA admitted the importance of several critically important antimicrobials to human health as well as the risk of transmitting resistance from animals to humans, it advised their continued use in food-producing and companion animals under the pretext of preserving animals' health and wellbeing. This recommendation, however, fails to address animal welfare concerns related to the overuse and misuse of antimicrobials. The contested Criterion C, used to establish the list, evaluates only possible replacement antimicrobials and does not consider that antimicrobials could be substantially reduced by responsible farming practices. The lower level of antimicrobial consumption in organic farming clearly supports this approach.

It is particularly alarming that the data sources used in EMA's advice do not give priority weighting to human medical opinions, despite the fact that this legal act is intended to safeguard crucial tools in human medicine in the context of rising AMR trends.

This proposal has already been scrutinised by the European Parliament's ENVI Committee, which unanimously criticised EMA's advice and urged the European Commission to fully apply the third sub-criterion referring to overriding public health interest. As risk manager, the prerogative of the European Commission is to decide if other antimicrobials might be included on the list in addition to the ones proposed by EMA's technical advice. Unfortunately, the European Commission has not made any change to EMA's advice against the mandate given by the European Parliament.

The European Commission has stated that the current list will be open for review and that other substances could be included in the future. However, it has not set a clear timeline for the periodical re-evaluation of the antimicrobials that are part of the list. Setting a clear process with a concrete timetable for the revision of the list would improve transparency and oversight of the process.

The undersigned organisations are concerned about the absence of vital antimicrobials for human health on the list, some of which are last-resort treatments for human health. If this list is adopted in its current form, these priority substances will continue to be used in food production to sustain poor farming practices. We therefore call on the European Commission to review the list and consider the evidence-based advice from civil society organisations throughout this process. Only in this way can the list become a meaningful tool for preserving the efficacy of key antimicrobials and ultimately tackling AMR. We also ask that the European Commission sets a clear timetable for the periodical revision of the list.

Supporting organisations:



Alliance to Save Our Antibiotics, Animal Welfare Foundation (AWF), Ärzte gegen Massentierhaltung - Doctors against factory farming, Biodynamic Federation Demeter International, BUKO Pharma-Kampagne, Compassion in World Farming EU (CIWF), Deutsche Umwelthilfe e.V., European Association of Hospital Pharmacists (EAHP), European Federation of Nurses Association (EFN), European Public Health Alliance (EPHA), Germanwatch, Health Care Without Harm Europe (HCWH), International Medical Cooperation Committee Denmark (IMCC-Denmark), Irish Doctors for the Environment, ProVeg International, PROVIEH e. V., Standing Committee of European Doctors (CPME), European Patient's Forum (EPF) and HOPE - European Hospital and Healthcare Federation